

### SWATI SPENTOSE PVT. LTD. UNIT-I

Mfg. Site Address: A-1/2102 & 2103, Phase-III, G.I.D.C, Vapi-396 195, Gujarat. India. Ph.: 0260-2433133, 2401533

CERTIFICATE OF ANALYSIS

Product Name	LIDOCAINE HYDROCHLORIDE (BP/EP)		Page No.: 1 of 2
Batch No.	LDH/718003	A. R. No.	FP/18/050
Batch size	1000.00 Kg	Released on	20/02/2018
Manufacturing Date	Feb-2018	Expiry Date	Jan-2023

Sr. No.	TEST	SPECIFICATION	RESULTS		
1.	Appearance	White or almost white, crystalline powder.	White crystalline powder		
2.	Solubility	Very soluble in water, freely soluble in ethanol (96%)	Complies		
3.	Identification				
4.	A) Melting point	74°C to 79°C, determined without previous drying.	78.2°C		
	B) IR spectrum	Should be concordant with Reference / Working Standard.	Complies		
	C) Colour test	A green colour is produced.	Complies		
	D) Chloride test	It gives reaction (a) of chlorides.	Complies		
5.	Appearance of solution	The solution S should be clear and colourless.	Complies		
6.	Нq	Between 4.0 and 5.5	5.22		
	Related Substances (By HPLC)				
	Impurity A	Not more than 0.01%	0.001%		
7.	Unspecified impurities	Not more than 0.10%	0.04%		
Total impurities		Not more than 0.5%	0.08%		
8.	Heavy metals	Maximum 5 ppm	Less than 5 ppm		
9.	Water content	5.5 % to 7.0 %, determined on 0.25 g. 6.20%			

Activity	Prepared By	Verified By	Approved By
Sign & Date	She sperio	Bay 107/16	41 Jack 20102118
Name	Ms. Jyotsana Nandan	Mr. Suresh Singh	Mr. S. K. Srivastava
Designation	Officer-QA	Manager-QC	Corporate Head-QA & QC

Fecha Entrada: 03-04-2019

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Míg. Site Address: A-1/2102 & 2103, Phase-III, G.I.D.C, Vapi-396 195, Gujarat. India. Ph.: 0260-2433133, 2401533

CERTIFICATE OF ANALYSIS

Product Name	LIDOCAINE HYDROCHLORIDE (BP/EP)		Page No.: 2 of 2
Batch No.	LDH/718003	A. R. No.	FP/18/050
Batch size	1000.00 Kg	Released on	20/02/2018
Manufacturing Date	Feb-2018	Expiry Date	Jan-2023

Sr. No.	TEST	SPECIFICATION	RESULTS
10.	Sulphated ash	Maximum 0.1%, determined on 1.0 g.	0.03%
11.	Assay (By Titration)	99.0 % to 101.0 % (anhydrous substance)	99.9%
12	Residual Solvent (By GC-HS)	Acetone: Not more than 5000 ppm	1011 ppm
12.		Toluene: Not more than 890 ppm	Not Detected

#### CONCLUSION:

In opinion of the undersigned, the above mentioned product COMPLIES as per BP-2017/EP-9.0 Specification.

#### STORAGE CONDITION:

Protected from light.

Activity	Prepared By	Verified By	Approved By
Sign & Date	St. 3c la la	Shy 30/01/18	f. Jan. 20102118
Name	Ms. Jyotsana Nandan	Mr. Suresh Singh	Mr. S. K. Srivastava
Designation	Officer-QA	Manager-QC	Corporate Head-QA & QC